

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: :
: Group Art Unit: 2151
Vladislav Olchanski et al. :
: Examiner: Karen C. Tang
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P.O. Box 1450
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REQUEST FOR PRE-APPEAL BRIEF CONFERENCE

Pursuant to the Pre-Appeal Brief Conference Pilot Program announced in the Official Gazette, Applicants hereby request a pre-appeal brief conference in the above-referenced patent application.

The present patent application was filed on November 20, 2001. On August 9, 2005, an initial non-Final Office Action was issued rejecting claims 1-25 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,650,932 to Menzie. On November 9, 2005, Applicants traversed the rejection of claims 1-25 with arguments and declarations under 37 C.F.R. 1.131 containing a showing of facts that clearly establish that the present application was conceived prior to May 15, 2000. Despite repeated attempts by the Applicants to convince the Examiner that the declarations clearly establish that the present application was conceived prior to May 15, 2000, thereby removing Menzie as a proper prior art reference, the Examiner continues to cite Menzie against the pending claims. On February 14, 2008, Applicants traversed the rejection of claims 1-25 with arguments, claim amendments, and newly added claims 26-30. On May 12, 2008, a new non-Final Office Action was issued rejecting claims 1-30 under 35 U.S.C. § 103(a) as being unpatentable over Menzie in view of U.S. Patent Application Publication No. 2004/0044274 to Bardy and further in view of U.S. Patent No. 6,223,164 to Seare. On August 12, 2008, Applicants traversed the rejection of claims 1-30 with additional arguments and claim amendments. Finally, on November 12, 2008, a Final Office Action was issued rejecting claims 1-21

and 23-30 under 35 U.S.C. § 103(a) as being unpatentable by U.S. Patent No. 3,675,640 to Gatts in view of Menzie and further in view of U.S. Patent No. 5,835,384 to Lin. Thus, Applicants respectfully submit that despite repeated attempts to convince the Examiner that the cited references clearly fail to teach, or even suggest, the claimed invention, the Examiner has maintained the rejection of claims 1-21 and 23-30, which is certain to be overturned on appeal. Rather than spending further time reiterating the same arguments clearly establishing that the cited references fail to teach, or even suggest, the claimed invention, Applicants have elected to pursue the Pilot Program.

As set forth in greater detail in Applicants' response dated January 9, 2009, the cited references Gatts, Menzie and Lin fail to disclose, or even suggest, all of the elements set forth in the pending claims.

I. THE OBVIOUSNESS REJECTION OF CLAIMS 1-21 AND 23-30

Regarding claims 1-21 and 23-30, the Examiner asserts that the claimed invention would have been obvious in view of Gatts, Menzie, and Lin. Applicants respectfully disagree. Regarding Gatts, Applicants respectfully submit that Gatts relates to an individual patient's health testing and operational procedure of a dynamic health evaluation system. In contrast, the present application relates to a decision analysis system that tracks comparative patient data over time (e.g., months or years) in order to draw inferences about the quality of the clinical care provided by ambulatory surgery centers in the out-patient surgery environment. More specifically, Gatts fails to disclose, or even suggest, collecting outcomes data sets associated with a medical procedure for a plurality of individuals (e.g., patients), as recited in independent claims 1, 11, 19, 24, and 25. Rather, Gatts discloses a dynamic health evaluation system for collecting an individual's health data. Furthermore, Gatts discloses collecting a single patient's health data during a single visit. In contrast, the present application claims collecting multiple outcomes data sets for one or more indicators associated with one or more medical procedures for a plurality of individuals in multiple periods of time via one or more user interfaces located at one or more user entities. Also, Gatts fails to disclose, or even suggest "a medical procedure," as recited in independent claims 1, 11, 19, 24, and 25. In contrast, Gatts merely discloses modifying dynamic treatment of an individual patient in accordance with the monitored data and to provide an optimized level of reconditioning therapy, and fails to disclose "a medical procedure."

Applicants also respectfully submit that Gatts fails to disclose, or even suggest, a method for collecting and reporting outcomes data for benchmarking medical procedures comprising "establishing a norm based at least in part on an outcomes data group, wherein the outcomes data group comprises a plurality of the first outcomes data sets," as recited in independent claims 1, 11, 19, 24, and 25. The Examiner relies on the abstract of Gatts to disclose "establishing a norm based at least in part on an outcomes data group," as claimed. However, Applicants respectfully submit that the Examiner erred in interpreting the abstract of Gatts. In contrast, Gatts simply discloses a computer programmed to compare a given individual against a preestablished norm. Specifically, Gatts discloses that the computer establishes how a specific individual should perform if he were in good physical and cardiopulmonary health by comparing the individual's data with clinical data stored in a memory bank. See, column 3, lines 3-12. Therefore, Gatts discloses providing a preestablished norm from a memory bank and not "establishing a norm based at least in part on an outcomes data group," as claimed.

Furthermore, the Examiner asserts, and Applicants agree, that Gatts fails to disclose, or even suggest, "collecting second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals," as claimed. The Examiner relies on column 2, lines 10-18, and column 3, lines 65-67, of Menzie to disclose such claimed limitation. Applicants respectfully disagree for several reasons. First of all, Applicants respectfully submit that Menzie is not a proper prior art reference for application against the claims of the present application as discussed in detail in Applicants response dated January 9, 2009, and numerous prior responses, including previously submitted inventor declarations under 37 C.F.R. 1.131. Secondly, Applicants respectfully submit that even if Menzie was a proper prior art reference (which it is not) and Gatts were to be combined with Menzie, the resulting combination would nevertheless fail to show each and every recitation of the claims. Specifically, Menzie discloses that collection devices 14a-14n are operable to measure physiological signals of a patient which are processed to provide a corresponding test result. Also, Menzie discloses that a trained analyst located at the processing center 20 may analyze the physiological data of the patient and the test results may remain at the processing center 20 for viewing over a web browser. See, e.g., column 4, lines 1-15. Thus, Menzie simply discloses collecting an individual patient's physiological data via collection devices 14a-14n and storing the physiological data at the processing

center 20, but does not disclose "collecting second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals," as claimed.

Assuming arguendo that Menzie does disclose "collecting second outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals," as alleged by the Examiner, Applicants further respectfully submit that it would not have been obvious to one of ordinary skill in the art at the time the invention was made to combine Gatts and Menzie. Indeed, Applicants respectfully submit that Gatts would teach away from Menzie under such an assumption. Specifically, Gatts discloses a dynamic health evaluation (DHE) system that illustrates what a specific person's physical performance capacity should be when evaluated against sufficient known clinical dynamic performance data. Simultaneously, the dynamic health evaluation (DHE) system prints out a proposed curve of performance for that same individual as if he were in a normal state of health. See, column 3, lines 13-23. Also, Gatts discloses that additional functions of the dynamic health evaluation (DHE) system may include comparing a curve of an individual's own performance and a theoretical curve of a similar individual in optimum physical condition and producing a recommended reconditioning level designed in terms of intensity, frequency, and duration to systematically program this patient to an optimum state of physical capacity that is consistent with his age and general health. See, column 3, lines 39-47. Meanwhile, Menzie would simply disclose a plurality of collection devices 14a-14n operable to measure physiological signals of a plurality of patients, as alleged by the Examiner. See, column 4, lines 1-3. Therefore, Applicants respectfully submit that it would not have been obvious to one of ordinary skill in the art at the time of the invention was made to collect and store physiological data from a plurality of individuals as allegedly disclosed by Menzie in order to evaluate an individual patient's physical condition as disclosed by Gatts.

Lastly, Applicants additionally respectfully submit that Gatts and Menzie, either alone or in combination, fail to disclose, or even suggest, a medical benchmarking system for multiple medical facilities (e.g., user entities and surgical centers), as claimed. Indeed, Gatts and Menzie, either alone or in combination, fail to disclose, or even suggest, a medical benchmarking system for multiple medical facilities (e.g., user entities and surgical centers) in any manner. In contrast, the present patent application claims a medical benchmarking system for multiple medical facilities (e.g., user entities and

surgical centers) wherein an outcomes monitoring report is generated comparing an outcomes result for a selected medical facility (e.g., a user entity or surgical center) to a norm based upon outcomes from multiple medical facilities (e.g., user entities and surgical centers). See, e.g., claims 1, 8, and 9. Thus, the present patent application is directed toward benchmarking a selected medical facility (e.g., a user entity or surgical center) against multiple other medical facilities (e.g., user entities and surgical centers). The present patent application also claims the broader application to any unit of observation (e.g., patient) for any type of activity (e.g., procedure) for any outcome (e.g., indicator) across any medical facility (e.g., ambulatory surgery center). Gatts and Menzie, either alone or in combination, clearly fail to disclose, or even suggest, such claimed features. Lin has no relevance to the claimed invention.

In view of the foregoing, Applicants respectfully submit that claims 1-21 and 23-30 are allowable over Gatts, Menzie, and Lin, either alone or in combination.

II. CONCLUSION

In view of the foregoing, it is respectfully submitted that the rejections of claims 1-21 and 23-30 are in error. Accordingly, for the foregoing reasons, Applicants request an appeal conference be convened so as to advise Applicants whether the Office will: 1) allow the present claims; 2) reopen prosecution and issue a new office action; or 3) allow this case to proceed to appeal.

Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account No. 50-0206, and please credit any excess fees to the same deposit account.

Respectfully submitted,

Hunton & Williams LLP

By: 

Thomas E. Anderson

Registration No. 37,063

Hunton & Williams LLP
1900 K Street, N.W.
Washington, D.C. 20006-1109
Telephone: (202) 955-1500
Facsimile: (202) 778-2201
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